NOVARTIS AG
Form 6-K
June 21, 2013

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated June 21, 2013

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

FDA grants Breakthrough Therapy designation to Novartis serelaxin (RLX030) for acute heart failure

- *Recognition by the US Food and Drug Administration (FDA) that RLX030 has the potential to address a serious unmet medical need*
- *If approved, RLX030 has the potential to be the first treatment breakthrough for Acute Heart Failure patients in 20 years(1),(2)*
- *RLX030 is the second Breakthrough Therapy designation by the FDA for Novartis investigational treatments, following LDK378*

Basel, June 21, 2013 Novartis announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation status to RLX030 (serelaxin), an investigational treatment for patients with acute heart failure (AHF). The FDA has concluded that RLX030 qualifies for a Breakthrough Therapy designation after considering the available clinical evidence which supports a substantial improvement over currently available therapies for AHF(3), a life-threatening illness.

The FDA s decision was supported by efficacy and safety results from the phase III RELAX-AHF trial, which also showed that patients who received RLX030 had a 37% reduction in mortality at 6 months after an acute heart failure episode compared to those who received conventional treatment(4).

Each year around 3.5 million AHF episodes happen in the US and EU alone(5); this is expected to increase further as the population ages. Every AHF episode contributes to a downward spiral of worsening heart failure and damage to vital organs, such as the heart and kidneys, which decreases the chance of the patient surviving another episode(6). There is an urgent need for new treatments that help relieve patients symptoms and protect the vital organs against damage during an AHF episode, as well as have the potential to increase life expectancy in the AHF patient population.

RLX030 is representative of Novartis strong commitment to develop innovative treatments for patients in areas of significant unmet need, said David Epstein, Division Head of Novartis Pharmaceuticals. Commonly used medicines for AHF only improve the immediate symptoms, so the additional effect on survival observed with RLX030 offers hope to patients and physicians .

RLX030 is currently being assessed by health authorities around the world including the FDA and the European Medicines Agency (EMA) for the treatment of AHF.

About RLX030 and Novartis commitment to heart failure

RLX030 (serelaxin) is a form of a naturally occurring hormone (human relaxin-2), present in both men and women(7), although its levels rise in pregnant women to help the body cope with the additional cardiovascular demands during pregnancy(8). RLX030 is proposed for administration on admission to the emergency room to patients

experiencing an AHF episode and is infused over a 48 hour period, in addition to conventional therapies.

In RELAX-AHF, RLX030 was shown to have both short and longer-term effects, helping patients breathe during and after an AHF episode, reducing the rate of heart failure worsening(4). Data from the clinical trial program has also shown that RLX030 s side effects are comparable to conventional therapy and it was generally well tolerated(4).

Another Novartis compound called LCZ696, an angiotensin receptor neprilysin inhibitor, is the first in a new class of dual acting drugs being evaluated for the treatment of chronic heart failure. A robust clinical development program including two global phase III studies (PARAGON-HF and PARADIGM-HF) is underway to fully assess the efficacy and safety profile of LCZ696.

About heart failure

Heart failure is a debilitating and potentially life-threatening condition where the heart cannot pump enough blood around the body. More than 15 million people suffer from heart failure globally and this number is increasing(9). The condition is often fatal when patients have one or repeated acute heart failure episodes. As an AHF episode approaches, patients become severely breathless and incapacitated and may rapidly gain weight due to fluid build-up in the lungs and around the body.

Patients experiencing an AHF episode need to be rushed to the emergency room for urgent treatment, making AHF the most common cause of hospitalization in patients over 65 years(10),(11).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as Breakthrough Therapy, potential, investigational, expected, commitment, hope, being assessed, proposed, being evaluated, underway, or similar expressions, or by ex implied discussions regarding potential approvals for RLX030, LDK378 or LCZ696, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that RLX030, LDK378 or LCZ696 will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding such products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in Novartis AG s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

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(2) Felker et al. Clinical t.rial of pharmacological therapies in acute heart failure syndromes, Circ Heart Fail. 2010;3:314-325.

(3) US Food and Drug Administration. Frequently Asked Questions: Breakthrough Therapies. Available at:

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(4) Teerlink et al. Serelaxin, recombinant human relaxin-2, for treatment of acute heart failure (RELAX-AHF): a randomised, placebo-controlled trial. Lancet, 2013;381:29-39.

(5) Novartis data on file: approximately 1.86 million diagnosed events in the US and 1.6 million in the top 5 EU countries.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date:	June 21, 2013	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting